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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/150,813	09/11/98	GRAINGER	D 295.027US1

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EXAMINER

MERTZ, P

ART UNIT PAPER NUMBER

1646

4

DATE MAILED: 03/03/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 1-4-99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 136(a).

Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☐ Claim(s) \_\_\_\_\_ is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☒ Claims 1-51 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

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## DETAILED ACTION

### *Election/Restriction*

Applicants are advised that claims 17-18, 20-28, 31-35, 39-45, 48-51 are improper Markush claims because the multiple elements recited therein: chemokine peptide 3, chemokine peptide 2, compound (IV), compound (V) and compound (VI), do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. The products are independent and distinct compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art compounds.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1, 3-12, drawn to a chemokine peptide 3, classified in class 530, subclass 351.

Group II. Claims 2, 6-10 and 13, drawn to a chemokine peptide 2, classified in class 530, subclass 351.

Group III. Claim 14, drawn to a compound of formula (IV), classified in class 564, subclass 152.

Group IV. Claim 15, drawn to a compound of formula (V), classified in class 564, subclass 463.

Group V. Claim 16, drawn to a compound of formula (VI), classified in class 562, subclass 553.

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Group VI. Claims 17, 20-22, 24-28, 31-35, 40-45, 48-51, drawn to a method of preventing or inhibiting an indication associated with a chemokine-induced activity comprising administering to a mammal a chemokine peptide 3, classified in class 424, subclass 85.1.

Group VII. Claims 17, 19, 20-22, 24-35, 39-45, 48-51, drawn to a method of preventing or inhibiting an indication associated with a chemokine-induced activity comprising administering to a mammal a chemokine peptide 2, classified in class 424, subclass 85.1.

Group VIII. Claims 18, 20-28, 31-36, 39-40, 45, 48-51, drawn to a method of preventing or inhibiting an indication associated with a chemokine-induced activity comprising administering to a mammal a compound of formula (IV), classified in class 514, subclass 616.

Group IX. Claims 18, 20-28, 31-35, 37, 39-40, 45, 48-51, drawn to a method of preventing or inhibiting an indication associated with a chemokine-induced activity comprising administering to a mammal a compound of formula (V), classified in class 514, subclass 613.

Group X. Claims 18, 20-28, 31-35, 38-40, 45, 48-51, drawn to a method of preventing or inhibiting an indication associated with a chemokine-induced activity comprising administering to a mammal a compound of formula (VI), classified in class 514, subclass 613.

Group XI. Claim 46, drawn to a chemokine antagonist peptide, classified in class 530, subclass 350.

Group XII. Claim 47, drawn to a chemokine peptide, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-V, XI-XII, are independent and distinct, each from the other, because they are compositions which possess characteristic differences in structure and function, that is distinct for each material composition, which cannot be exchanged.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as antigen in the production of antibodies.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as antigen in the production of antibodies.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as antigen in the production of antibodies.

Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

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as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as antigen in the production of antibodies.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as antigen in the production of antibodies.

Inventions XI-XII and VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VI-X are independent and distinct, each from the other, because the methods are practiced with materially different materials which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. The only feature in common in the instant inventions is "a method of preventing or inhibiting an indication associated with a chemokine-induced activity", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as IL-8. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different

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Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of chemokine peptide 3 with the claimed method would not necessarily reveal art for an association of chemokine peptide 2 with the claimed method. Similarly, a search of the literature with any of compounds IV-VI would not necessarily reveal art for an association of chemokine peptide 3 or 2 with the claimed method.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a) (1) and (a)(2). However, the

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specification fails to comply with one or more of the requirements of 37 CFR § 1.821 through 1.825 as follows: Specifically, no sequence listing has been provided which includes the sequences presented in the specification. Applicants need to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the copy of the paper and computer readable copies are the same and, where applicable, includes no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.821(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires that a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification where ever a reference is made to that sequence. For rules Applicant may call (703) 308-4216. See M.P.E.P. 2422.04.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner

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February 26, 1999



Application No.: 09/150,813

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**

COPY FOR [ ] File [ ] Applicant